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Clinical and Radiological Outcomes of the Eminent Spine® Diamondback®
Pedicle Screw System and the Boa Constrictor® Cross-Link:

Introduction

Posterior Lumbar Pedicle Screw fixation is an accepted treatment for Degenerative Spondylolisthesis, Degenerative Disk Disease and Post-Laminectomy Syndrome, Stenosis, Scoliosis, and other conditions. The Eminent Spine ("ES®") pedicle screw system ("Diamondback®") can be used in conjunction with the ES® cross-link ("Boa Constrictor®"). The Diamondback® Pedicle screw system was developed specifically as a low profile polyaxial pedicle screw system. The Boa Constrictor® cross-link was designed to enhance construct stability, simplify application and minimize dural impingement.

Purpose

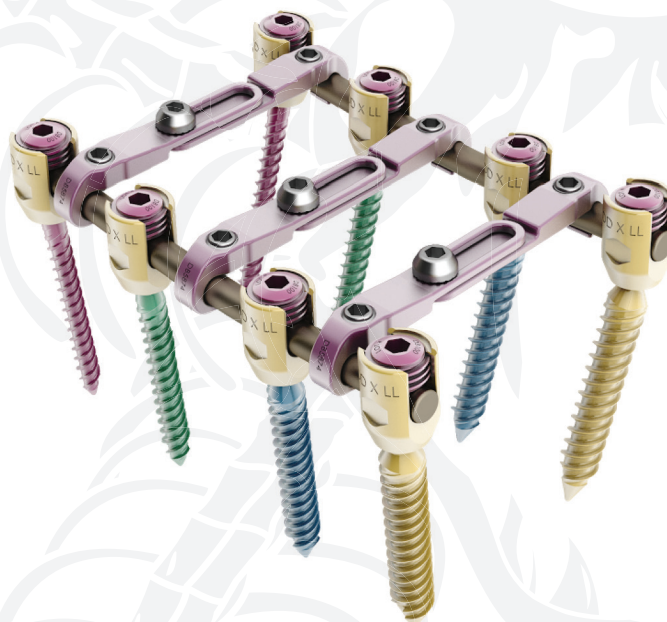
The purpose of this study is to evaluate the very early results of the Diamondback® and Boa Constrictor® in regard to screw fracture, screw disassemble, set screw stripping, and set screw popping off.

Demographic (242 patients)	Diagnosis	Comorbidity
Males 113 Females 129 Age (30-78) Weight (120-365 lbs)	Degenerative Spondylolisthesis 64 Degenerative Disk Disease and Post-Laminectomy Syndrome 56 Degenerative Disk Disease and Stenosis 57 Degenerative Disk Disease and Diskogenic Pain 29 Degenerative Disk Disease and HNP 46 Degenerative Disk Disease and Scoliosis 6	Smoker 47 HTN 70 Diabetes 48 Previous Lumbar Surgery 64 Other 4

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Device Description

The Diamondback® pedicle screw system can be used as an adjunct device to supplement posterior lumbar fusion. The screw consists of titanium, and is available in four different diameters. (4.5,5.5,6.5,7.5mm) The Diamondback® screws are self tapping, and are available in single, double and triple lead thread pitch. Reduction screws are also available. The Diamondback® tulip is tapered with a friction head which makes the tulip not floppy. The Boa Constrictor® cross-link is offered in 3 different sizes. It is designed for easy implantation and minimizes dural impingement.

Methods

This study examines 242 patients, from July 2010 to present, who were candidates for posterior lumbar fusion. Diagnoses include degenerative spondylolisthesis and degenerative disk disease with post-laminectomy syndrome, diskogenic pain, HNP, stenosis and scoliosis. All devices were inserted using an open posterior approach. All patients received an ES® Diamondback® pedicle screw device. 207 bilateral fusion patients received an ES® Boa Constrictor® implant. Radiographic assessment includes plain x-rays at 2 and 6 weeks and at 3, 6 and 12 months based on date of surgery.

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Lumbar Levels	Unilateral	Bilateral
T10-L3		1
T12-L3		1
T12-L5		1
L1-L4	7	2
L1-S1		7
L1-S2		1
L2-S1	5	25
L2-L4	1	2
L3-S1	7	46
L3-L4		1
L4-S1	14	75
L5-S1	7	12
L2-L5	1	3
L3-L5	4	11
L4-L5	1	19

Boa Constrictor® Sizes	
Small (32-42mm)	5
Medium (42-58mm)	398
Large (58-74mm)	85
Total	488

Diameter of Screw	
4.5mm	20
5.5mm	103
6.5mm	1190
7.5mm	446
Total	1,759



Diamondback®
(Pedicle Screw)

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Technique

(*Surgeon must review technique manual prior to insertion.)

Surgeon must review technique manual prior to insertion.

Results

Of the 242 patients included in the study, each patient completed a 2 and 6 week and 3, 6, and 12 month follow up based on date of surgery. Lateral and AP x-rays were taken at that time. No patient had a Diamondback® screw fracture, or screw disassemble and no set screws popped off. 2 set screw stripped. There was no Boa Constrictor® set screw fracture, stripping or pop off. There were no implant failures.

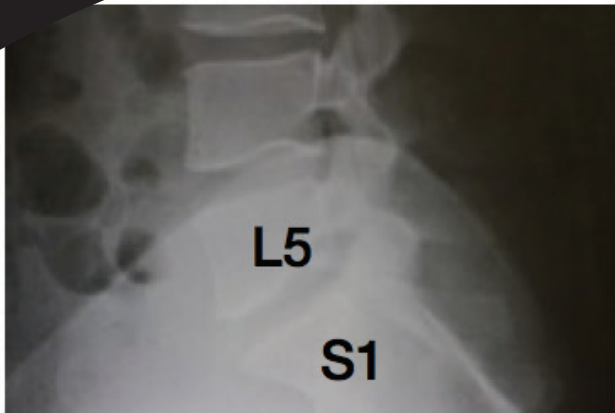
Discussion

This study has shown that the Eminent Spine® Diamondback® pedicle screw system and the Boa Constrictor® cross-link system are devices that can be safely implanted. This study has demonstrated that the Diamondback® and Boa Constrictor® are safe and effective products. There was no screw breakage, set screw failure, or any implant failure. Clinical studies are currently being performed to further evaluate the products.

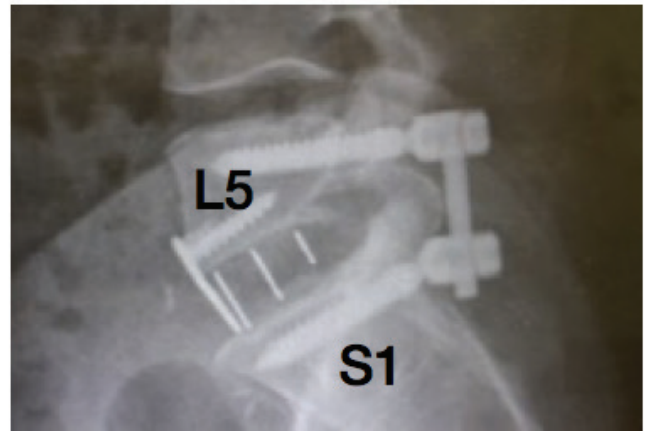
Complications	
Diamondback® Set Screw Popped Off	0
Diamondback® Set Screw Stripped	2
Diamondback® Screw Fracture	0
Diamondback® Screw Disassembled	0
Diamondback® Rod Popped Out	0
Boa Constrictor® Set Screw Popped Off	0
Boa Constrictor® Set Screw Stripped	0
Boa Constrictor® Set Screw Fracture	0
Boa Constrictor® Disassembled	0

1 Level: Unilateral 360 L5/S1 Diamondback® Pedicle Screw System & Fang Plate®

40 y/o WF with DDD and Recurrent Disk Herniation



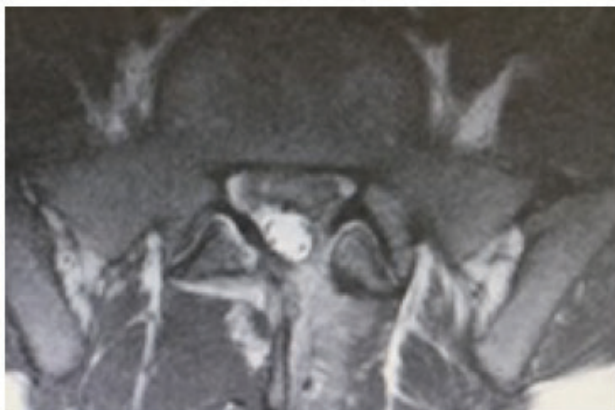
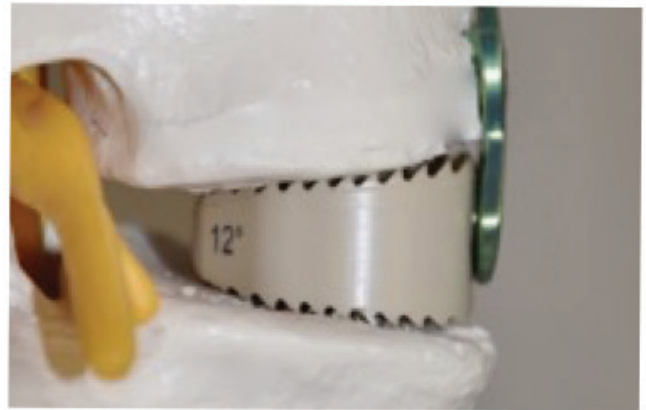
Pre-Op



Post-Op



Pre-Op



Pre-Op

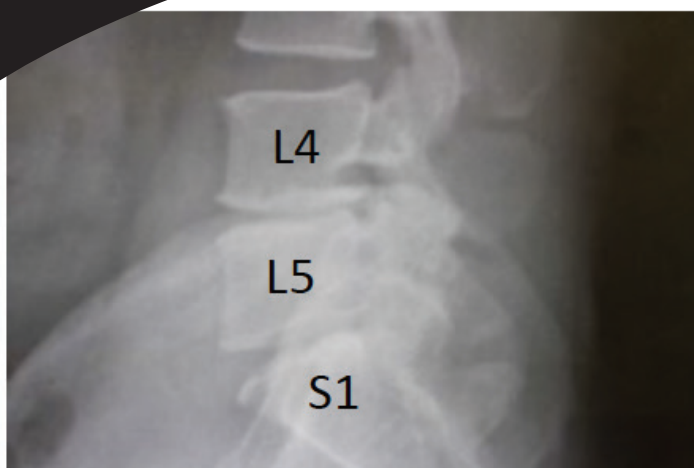


Post-Op

2 Level: L4/5, L5/S1

Diamondback® Pedicle Screw System

41 y/o WM with DDD and Post-Laminectomy Syndrome



Pre-Op



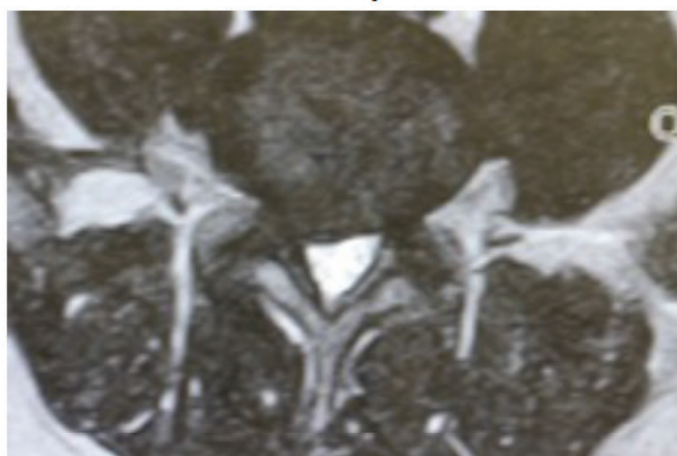
Post-Op



Pre-Op



Post-Op

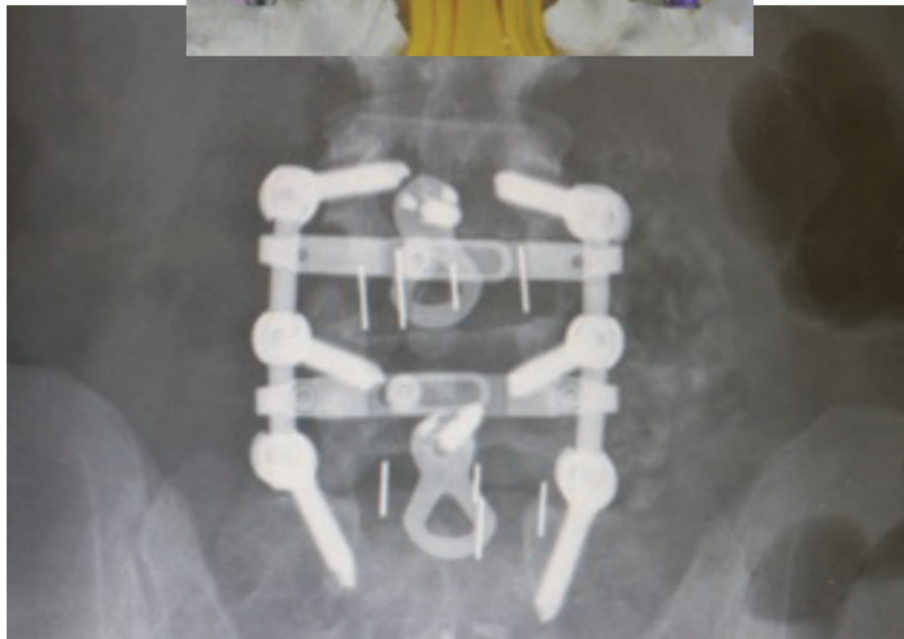
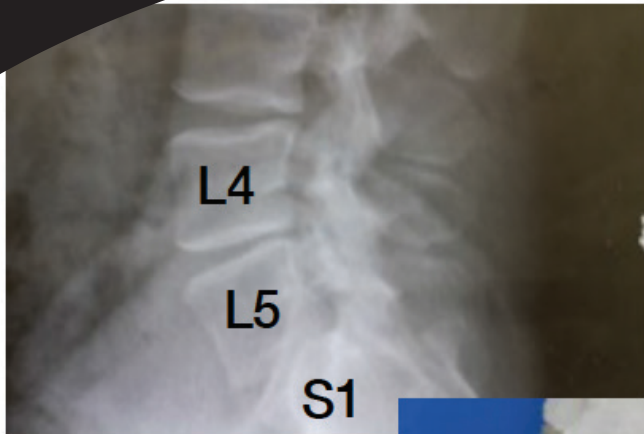


Pre-Op



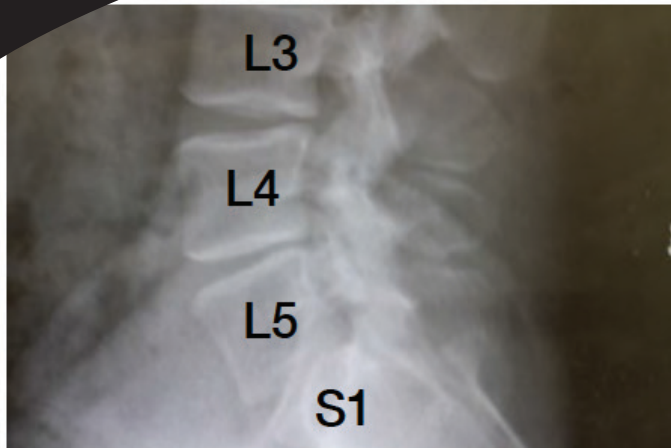
2 Level: L4/L5, L5/S1 360 Fusion Diamondback® Pedicle Screw System & Boa Constrictor® Cross-Link

45 y/o WF with DDD and Diskogenic Pain



2 Level: L3/L4, L4/L5 360 Fusion Diamondback® Pedicle Screw System & Boa Constrictor® Cross-Link

48 y/o WM with DDD and Diskogenic Pain



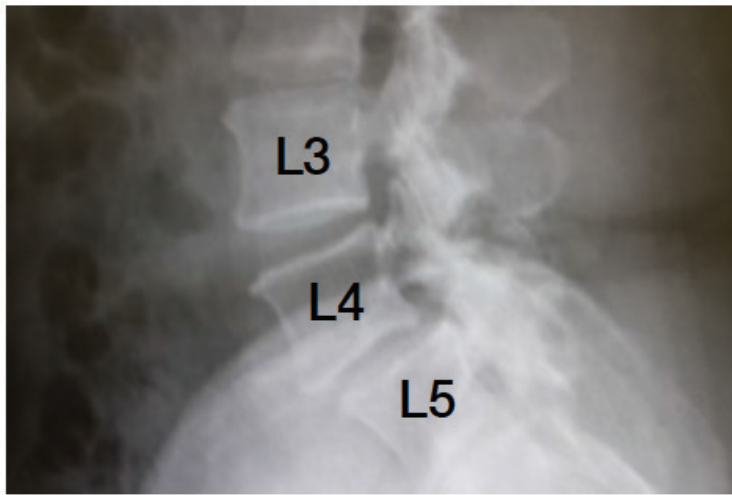
Fang Plate placed per vascular anatomy



2 Level: L3/L4, L5/S1 360

Diamondback® Pedicle Screw System & Boa Constrictor® Cross-Link

55 y/o WF with DDD and Spondylolisthesis

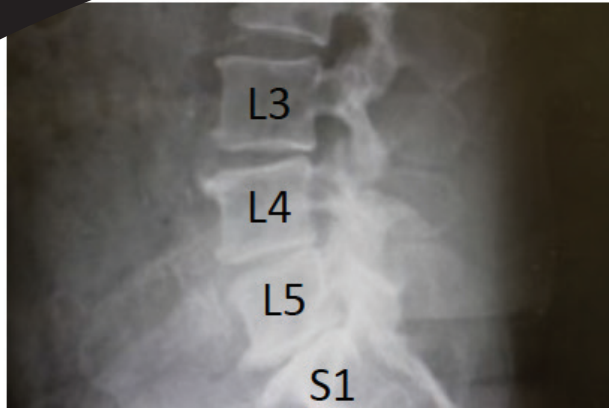


Pre-Op → Post-Op



3 Level: L3/L4, L4/L5, L5/S1 Diamondback® Pedicle Screw System & Boa Constrictor® Cross-Link

48 y/o WM with Multi-Level Lumbar Stenosis



3 Level: L3/L4, L4/L5, L5/S1

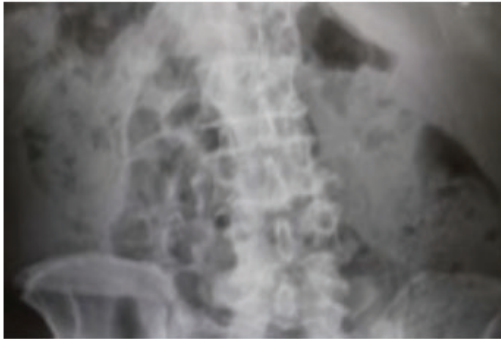
Diamondback® Pedicle Screw System & Boa Constrictor® Cross-Link

67 y/o WM with DDD & Stenosis



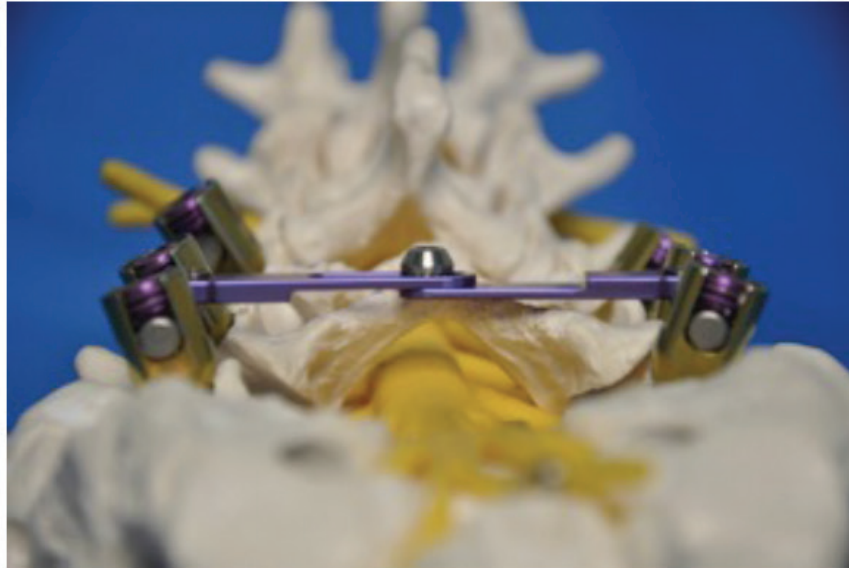
4 Level: L2/L3, L3/L4, L4/L5, L5/S1 Diamondback® Pedicle Screw System & Boa Constrictor® Cross-Link

71 y/o with DDD & Multi-Level Stenosis



5 Level: L1/L2, L2/L3, L3/L4, L4/L5, L5/S1 Diamondback® Pedicle Screw System & Boa Constrictor® Cross-Link

72 y/o WM with DDD and Multi-Level Stenosis



Lumbar Revision: L1/L2, L2/L3, L3/L4, L4/L5, L5/S1, S1/S2 Diamondback® Pedicle Screw System & Boa Constrictor® Cross-Link

75 y/o with DDD & Post-Laminectomy Syndrome



Luque rectangle

